

Claim Listing:

1. (withdrawn) A method of treating, managing or preventing an autoimmune disorder which comprises administering to a patient in need of such treatment a therapeutically or prophylactically effective amount of clofarabine or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, clathrate, prodrug or metabolite thereof.
2. (withdrawn) The method of claim 1 wherein the autoimmune disorder is a disorder of the nervous system, the blood, the gastrointestinal system, the endocrine glands, the skin, the musculoskeletal system, the connective tissue or combinations thereof.
3. (withdrawn) The method of claim 1 wherein the autoimmune disorder is Alopecia Areata, Ankylosing Spondylitis, Antiphospholipid Syndrome, Autoimmune Addison's Disease, Autoimmune Hemolytic Anemia, Autoimmune Hepatitis, Autoimmune Uveitis, Autoimmune Oophoritis, Autoimmune Orchitis, Behcet's Disease, Bullous Pemphigoid, Cardiomyopathy, Celiac Sprue Dermatitis, Chronic Fatigue Immune Dysfunction Syndrome (CFIDS), Chronic Inflammatory Demyelinating Polyneuropathy, Churg Strauss Syndrome, Cicatricial Pemphigoid, CREST Syndrome, Cold Agglutinin Disease, Crohn's Disease, Dermatitis Herpetiformis, Essential Mixed Cryoglobulinemia, Fibromyalgia Fibromyositis, Graves' Disease, Guillain Barre, Hashimoto's Thyroiditis, Idiopathic Pulmonary Fibrosis, Idiopathic Thrombocytopenia Purpura (ITP), IgA Nephropathy, Insulin dependent Diabetes, Immune Mediated Diabetes, Juvenile Arthritis, Lichen Planus, Meniere's Disease, Mixed Connective Tissue Disease, Myasthenia Gravis, Pemphigus Vulgaris, Pernicious Anemia, Polyarteritis Nodosa, Polychondritis, Polyglandular Syndromes, Polymyalgia Rheumatica, Polymyositis and Dermatomyositis, Primary Agammaglobulinemia, Primary Biliary Cirrhosis, Psoriasis, Raynaud's Phenomenon, Reiter's Syndrome, Rheumatic Fever, Sarcoidosis, Scleroderma, Sjogren's Syndrome, Stiff Man Syndrome, Takayasu Arteritis, Temporal Arteritis, Giant Cell Arteritis, Ulcerative Colitis, Uveitis, Vasculitis, Vitiligo or Wegener's Granulomatosis.
4. (withdrawn) The method of claim 1 wherein the patient is a mammal.

5. (withdrawn) The method of claim 4 wherein the mammal is a human.
6. (withdrawn) The method of claim 5 wherein the human is an adult.
7. (withdrawn) The method of claim 5 wherein the human is an adolescent.
8. (withdrawn) The method of claim 5 wherein the human is a child.
9. (withdrawn) The method of claim 5 wherein the human is an infant.
10. (withdrawn) The method of claim 1 further comprising the administration of an additional therapeutic agent.
11. (withdrawn) The method of claim 10 wherein the additional therapeutic agent is an antibiotic, an antiemetic agent, an antidepressant, and antifungal agent, an antiinflammatory agent, an antiviral agent, an immunomodulatory agent, a .beta.-interferon, an alkylating agent, a hormone or a cytokine.
12. (withdrawn) The method of claim 1 wherein the therapeutically or prophylactically effective amount is greater than 1 mg/kg/day.
13. (withdrawn) The method of claim 1 wherein the therapeutically or prophylactically effective amount of clofarabine is from about 5 mg/kg/day to about 75 mg/kg/day.
14. (withdrawn) The method of claim 13 wherein the therapeutically or prophylactically effective amount of clofarabine is from about 20 mg/kg/day to about 60 mg/kg/day.

15. (withdrawn) The method of claim 14 wherein the therapeutically or prophylactically effective amount of clofarabine is from about 40 mg/kg/day to about 50 mg/kg/day.
16. (withdrawn) The method of claim 1 wherein the therapeutically or prophylactically effective amount of clofarabine is administered parenterally.
17. (withdrawn) The method of claim 1 wherein the therapeutically or prophylactically effective amount of clofarabine is administered orally.
18. (cancelled)
19. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim ~~18-31~~ wherein said dosage form is suitable for parenteral, transdermal, mucosal or oral administration to a patient.
20. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim 19 wherein said mucosal administration is nasal administration.
21. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim 19 wherein said mucosal administration is buccal administration.
22. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim 19 wherein said mucosal administration is sublingual administration.
23. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim 19 wherein said mucosal administration is rectal administration.
24. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim ~~19-31~~ wherein said dosage form is a capsule ~~or a tablet~~.

25. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim ~~19-31~~ wherein said dosage form is an aerosol.
26. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim ~~19-31~~ wherein said dosage form is a reconstitutable powder.
27. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim ~~18-31~~ wherein the amount of clofarabine is from about 5 mg to about 1000 mg.
28. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim 27 wherein the amount of clofarabine is from about 100 mg to about 500 mg.
29. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim 28 wherein the amount of clofarabine is from about 200 mg to about 350 mg.
30. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim ~~18-31~~ wherein the dosage form is sterile.
31. (currently amended) A high dose pharmaceutical composition in unit dosage form for the treatment of an autoimmune disorder ~~which comprises about 5 to about 1000 mg comprising a therapeutically effective amount~~ of clofarabine, or a pharmaceutically acceptable salt, hydrate, clathrate, solvate, prodrug, metabolite or stereoisomer thereof and a pharmaceutically acceptable carrier, wherein the therapeutically effective amount of clofarabine is sufficiently high to treat the autoimmune disorder.
32. (withdrawn) A method of treating multiple sclerosis which comprises administering to a patient in need of such treatment from about 1.25 mg/kg/day to about 80 mg/kg/day of clofarabine or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, clathrate, prodrug or metabolite thereof.

33. (withdrawn) The method of claim 32 which comprises administering from about 50 mg/kg/day to about 75 mg/kg/day of clofarabine or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, clathrate, prodrug or metabolite thereof.
34. (withdrawn) The method of claim 33 which comprises administering from about 20 mg/kg/day to about 60 mg/kg/day of clofarabine or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, clathrate, prodrug or metabolite thereof.
35. (withdrawn) The method of claim 33 which comprises administering from about 40 mg/kg/day to about 50 mg/kg/day of clofarabine or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, clathrate, prodrug or metabolite thereof.
36. (withdrawn) The method of claim 32 wherein the therapeutically or prophylactically effective amount of clofarabine is administered parenterally.
37. (withdrawn) The method of claim 32 wherein the therapeutically or prophylactically effective amount of clofarabine is administered orally.
38. (withdrawn) A method of treating psoriasis which comprises administering to a patient having psoriasis a therapeutically effective amount of clofarabine or a pharmaceutically acceptable salt, stereoisomer or solvate thereof.
39. (withdrawn) The method of claim 38, wherein clofarabine or a pharmaceutically acceptable salt, stereoisomer or solvate thereof is administered in a gel.
40. (withdrawn) The method of claim 39 wherein the therapeutically or prophylactically effective amount of clofarabine is from about 5 mg/kg/day to about 75 mg/kg/day.
41. (withdrawn) The method of claim 39 wherein the therapeutically or prophylactically

effective amount of clofarabine is from about 20 mg/kg/day to about 60mg/kg/day.

42. (withdrawn) The method of claim 39 wherein the therapeutically or prophylactically effective amount of clofarabine is from about 40 mg/kg/day to about 50 mg/kg/day.

43. (withdrawn) The method of claim 38 further comprising the administration of an additional therapeutic agent.

44. (withdrawn) The method of claim 43 wherein the additional therapeutic agent is an antibiotic, an antiemetic agent, an antidepressant, and antifungal agent, an anti-inflammatory agent, an antiviral agent, an immunomodulatory agent, a β -interferon, an alkylating agent, a hormone or a cytokine.

45. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim ~~19-31~~ wherein said dosage form is a gel.

46. (currently amended) The pharmaceutical composition ~~dosage form~~ of claim 27 wherein said dosage form is a gel.

47. (withdrawn) The method of claim 1, wherein a pharmaceutically acceptable salt of clofarabine is administered.

48. (withdrawn) The method of claim 1, wherein clofarabine is administered as a free base.

49. (withdrawn) The method of claim 38, wherein a pharmaceutically acceptable salt of clofarabine is administered.

50. (withdrawn) The method of claim 38, wherein clofarabine is administered as a free base.

51. (withdrawn) The method of claim 38, wherein the solvate is a hydrate.
52. (new) The pharmaceutical composition of claim 31, wherein said dosage form is a tablet.
53. (new) The pharmaceutical composition of claim 31, wherein the autoimmune disorder is Alopecia Areata, Ankylosing Spondylitis, Antiphospholipid Syndrome, Autoimmune Addison's Disease, Autoimmune Hemolytic Anemia, Autoimmune Hepatitis, Autoimmune Uveitis, Autoimmune Oophoritis, Autoimmune Orchitis, Behcet's Disease, Bullous Pemphigoid, Cardiomyopathy, Celiac Sprue Dermatitis, Chronic Fatigue Immune Dysfunction Syndrome (CFIDS), Chronic Inflammatory Demyelinating Polyneuropathy, Churg Strauss Syndrome, Cicatricial Pemphigoid, CREST Syndrome, Cold Agglutinin Disease, Crohn's Disease, Dermatitis Herpetiformis, Essential Mixed Cryoglobulinemia, Fibromyalgia Fibromyositis, Graves' Disease, Guillain Barre, Hashimoto's Thyroiditis, Idiopathic Pulmonary Fibrosis, Idiopathic Thrombocytopenia Purpura (ITP), IgA Nephropathy, Insulin dependent Diabetes, Immune Mediated Diabetes, Juvenile Arthritis, Lichen Planus, Meniere's Disease, Mixed Connective Tissue Disease, Myasthenia Gravis, Pemphigus Vulgaris, Pernicious Anemia, Polyarteritis Nodosa, Polychondritis, Polyglandular Syndromes, Polymyalgia Rheumatica, Polymyositis and Dermatomyositis, Primary Agammaglobulinemia, Primary Biliary Cirrhosis, Psoriasis, Raynaud's Phenomenon, Reiter's Syndrome, Rheumatic Fever, Sarcoidosis, Scleroderma, Sjogren's Syndrome, Stiff Man Syndrome, Takayasu Arteritis, Temporal Arteritis, Giant Cell Arteritis, Ulcerative Colitis, Uveitis, Vasculitis, Vitiligo or Wegener's Granulomatosis.
54. (new) The pharmaceutical composition of claim 31, wherein the autoimmune disorder is multiple sclerosis.
55. (new) The pharmaceutical composition of claim 31, wherein the autoimmune disorder is Crohn's Disease.